AUTHORITY: 21 U.S.C. 351, 352, 360c, 360d, 360gg–360ss, 371, 374; 42 U.S.C. 262, 264.

SOURCE: 62 FR 25497, May 9, 1997, unless otherwise noted.

§ 898.11 Applicability.

Electrode lead wires and patient cables intended for use with a medical device shall be subject to the performance standard set forth in § 898.12.

§ 898.12 Performance standard.

(a) Any connector in a cable or electrode lead wire having a conductive connection to a patient shall be constructed in such a manner as to comply with subclause 56.3(c) of the following standard:

International Electrotechnical Commission (IEC)
601–1: Medical Electrical Equipment
601–1 (1988) Part 1: General requirements for safety
Amendment No. 1 (1991)
Amendment No. 2 (1995).

(b) Compliance with the standard shall be determined by inspection and by applying the test requirements and test methods of subclause 56.3(c) of the standard set forth in paragraph (a) of this section.

§ 898.13 Compliance dates.

The dates for compliance with the standard set forth in § 898.12(a) shall be as follows:

(a) For electrode lead wires and patient cables used with, or intended for use with, the following devices, the date for which compliance is required is May 11, 1998:

LISTING OF DEVICES FOR WHICH COMPLIANCE IS REQUIRED EFFECTIVE
May 11, 1998

Phase	Product code	21 CFR section	Class	Device name
1	73 BZQ	868.2375	II	Monitor, Breathing Frequency.
1	73 FLS	868.2375	II	Monitor (Apnea Detector), Ventilatory Effort.
1	74 DPS	870.2340	II	Electrocardiograph.
1	74 DRG	870.2910	II	Transmitters and Receivers, Physiological Signal, Radio Frequency.
1	74 DRT	870.2300	II	Monitor, Cardiac (including Cardiotachometer and Rate Alarm).
1	74 DRX	870.2360	II	Electrode, Electrocardiograph.
1	74 DSA	870.2900	II	Cable, Transducer and Electrode, Patient (including Connector).
1	74 DSH	870.2800	II	Recorder, Magnetic Tape, Medical.
1	74 DSI	870.1025	III	Detector and Alarm, Arrhythmia.
1	74 DXH	870.2920	II	Transmitters and Receivers, Electrocardiograph, Telephone.

(b) For electrode lead wires and patient cables used with, or intended for use with, any other device, the date for which compliance is required is May 9, 2000.

§ 898.14 Exemptions and variances.

(a) A request for an exemption or variance shall be submitted in the form of a petition under §10.30 of this chapter and shall comply with the requirements set out therein. The petition shall also contain the following:

(1) The name of the device, the class in which the device has been classified, and representative labeling showing the intended uses(s) of the device;

(2) The reasons why compliance with the performance standard is unnecessary or unfeasible;

(3) A complete description of alternative steps that are available, or that the petitioner has already taken, to ensure that a patient will not be inadvertently connected to hazardous voltages via an unprotected patient cable or electrode lead wire for intended use with the device; and

(4) Other information justifying the exemption or variance.

(b) An exemption or variance is not effective until the agency approves the request under § 10.30(e)(2)(i) of this chapter.

EFFECTIVE DATE NOTE: At 62 FR 25477, May 9, 1997, § 898.14 was stayed pending Office of